to three N in a ring--. The basis for this amendment is found at page 4, lines 1-3 where the term "one or more N atoms" was defned by reference to seven specific heterocyclic groups which contained from 1 to 3 N atoms. Based on this disclosure, the claims have been amended to insert three as the maximum number of nitrogen atoms in eterocyclic groups defined by the claims. For these reason, it is requested that this ground of rejection be withdrawn.

The Examiner also questioned the enablement of the claims based on the definition of R_1 - R_6. The specification is directed to one who is skilled in the art and as such it does not have to recite that which is well known in the art. One who is skilled in this art can readily prepare the various compounds of claim 1 without the exercise of inventive faculty. The Examiner has not pointed to any particular compound which cannot be made based on the present specification and the skill of the art.

The applicants have previously submitted a copy of U.S. 6,303,622 which has been granted to the present applicants. The scope of the claims in that granted patent are not materially deferent from the claims of the present application with regard to the substituents that are present on the benzo[c]quinolizine derivatives. The granted patent should be considered in connection with the determination of scope and the definiteness of the claims of the present application. The definitions of R^1, R_2, R_3, R_4 and R_6 in the granted patent are similar to the definitions of R^1, R_2, R_3, R_4 and R_6 in the present application and are not unduly broad considering the level of skill in the art of pharmaceutical chemistry.

It is not necessary for an applicant for a patent to carry out any tests for activity in order to comply with 35 U.S.C.§112, irst paragraph. The basis for determinming if a patent application contains an enabling disclosure is whether or not one skilled in the art can make and use the claimed subject matter, based on the disclosure and the knowledge of the art. Every possible species need not be made and tested. It is only necessary that the disclosure be sufficient to enable one of ordinary skill in the art to practice the invention without undue

experimentation. The Examiner has not addressed the question of exactly how much experimentation would be required to prctice the invention and has not addressed the question of what is the level of skill in the pharmaceutical art. When these factors are considered, it is believed that the specification is in full compliance with 35 U.S.CC. §112, first paragraph and the presnet ground of rejection should be withdrawn.

Claims 1 was rejected under 35 U.S.C.§112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter that the applicant regards as the invention.

Reconsideration is requested.

As noted above, the text of claim 1 has been amended to revise the phrase "one or more N" to read --one to three N". The claims have been amended to singularize the term "compounds" and to insert the term "A" in the claims as suggested by the Examiner. This amendment obviates the basis for the rejections under 35 U.S.C.§112, second paragraph and it is requested that these rejections be withdrawn.

It is assumed that Claim 3 is allowable except that it is dependent on a rejected claim. Since it is believed that claim 1 is now in allowable form, it is not necessary to amend claim 3.

Claim 28 was rejected under 35 U.S.C.§112, first paragraph because the specification does not give enablement for the method of treating all of the diseases which are unrelated.

Reconsideration is requested.

It is believed that the claim that was the subject of the present ground of rejection is claim 27. The text oif claim 27 points out that a method for the inhibition of 5α reductase- and or 5α reductase-II iso-enzyme. The claim also specifies five specific disease states that are well known to respond to treatment with 5α reductase inhibitors. The specifiaction has test data that shows that compounds disclosed by the applicants have the ability to inhibit 5α reductase. This is set forth at pages 18 and 19 of the specification. It is well known that compounds which inhibit 5α reductase are useful for treating

prostatic hypertrophy, prostate cancer, acne, male pattern baldness and hirsutism. See claim 9 in the attached copy of U.S. 5,543,406. FGor these reasons, it is requested that this ground of rejection be reconsidered and withdrawn.

New claim 29 points out the preferred heterocycle substituents set forth on page 4, lines 1-23 of the specification.

An early and favorable action is earnestly solicited.

Respectfully submitted,

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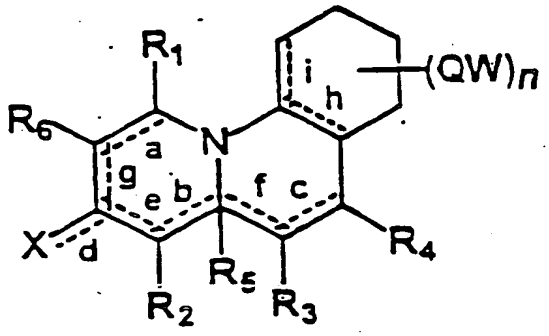
I hereby certify that this correspondence is being deposited with the United States Postal Service as first class mail in an envelope addressed to: Commissioner for Patents, Washington, D.C. 20231, on 11/12/02

Marked up copy of amended claims:

1. (twice amended) A [F]fully and partially reduced benzo(c)quinolizine compound[s] of formula (1):



(I)

wherein:

R_1, R_2, R_3, R_4 and R_6, which are the same or different, are chosen from the group consisting of: H, C_{1-8} alkyl, C_{2-8} alkenyl, C_{2-8} alkynyl, cyclopropane, cyclobutane, cyclopentane, cyclohexane, cycloheptane, cyclooctane, norbornane, canphane, adamantane, phenyl, biphenyl, naphthyl, saturated or aromatic heterocycle containing one to three [or more] N atoms, halogen, CN, azide, NRR', C_{1-8} alkylamino, arylamino, C_{1-8} alkyloxy, aryloxy, COOR, CONRR', C(=O)R, wherein R and R', which are the same or different, are chosen from the group consisting of H, C_{1-8} alkyl, cyclopropane, cyclobutane, cyclopentane, cyclohexane, cycloheptane, cyclooctane, norbornane, canphane, adamantane, phenyl, biphenyl, naphthyl, saturated or aromatic heterocycle containing one [or more] to three N atoms[,] or naphthyl-C_{1-8};

R_5 is chosen from the group consisting of: H, C_{1-8} alkyl, C_{1-8}alkyl-phenyl, biphenyl, naphthyl, COOR, CN, phenyl, saturated or aromatic heterocycle containing one to three [or more] N atoms, C_{1-8} alkyl-saturated or aromatic heterocycle containing one or more N atoms; C_{1-8} alkyl saturated or aromatic heterocycle containing one to three [or more] N atoms-ribose phosphate;

X is chosen from the group consisting of: O, C(=O)R, COOR, NO_2, and CONNR', wherein R and R' are as above defined;

Q is chosen from the group consisting of single-bond, C_{1-8} alkyl,

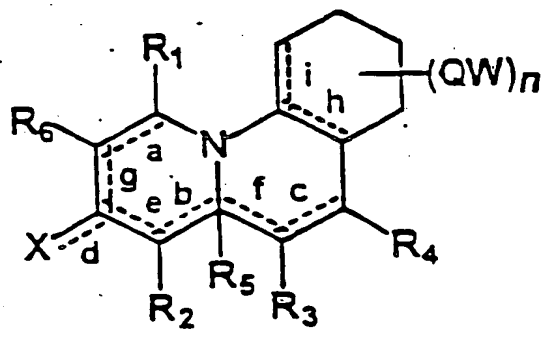
C_{2-8} alkenyl, C_{2-8} alkynyl, cyclopropane, cyclobutane, cyclopentane, cyclohexane, cycloheptane, cyclooctane, norbornane, canphane, adamantane, CO, CONR, and NR, where R is as above defined;
W is chosen from the group consisting of H, C_{1-8} alkyl, C_{2-8} alkenyl, C_{2-8} alkynyl, cyclopropane, cyclobutane, cyclopentane, cyclohexane, cycloheptane, cyclooctane, norbornane, canphane, adamantane, trifluoromethyl, C_{1-8} alkoxy, C_{1-8} alkoxy-C_{1-8} alkyl, phenyl, biphenyl, naphthyl-C_{1-8} alkyl, phenyl, biphenyl, naphthyl, phenyloxy, biphenyloxy, naphthyloxy, phenylamino, biphenylamino, naphthylamino, C_{1-8} alkyl-carbonyl, phenylcarbonyl, biphenylcarbonyl, naphthylcarbonyl, phenylcarboxyl, biphenylcarboxyl, naphthylcarboxyl, phenylcarboxyamide, biphenylcarboxyamide, naphthylcarboxyamide, halogen, CN, NRR', C_{1-8} alkylamino, saturated or aromatic heterocycle containing one [or more] to three N atoms wherein the groups alkyl, alkenyl, alkynyl, cyclopropane, cyclobutane, cyclopentane, cyclohexane, cycloheptane, cyclooctane, norbornane, canphane, adamantane, phenyl, biphenyl, naphthyl, saturated or aromatic heterocycle containing one [or more] to three N atoms, can be substituted;
n is an integer comprised between 1 and 4;
the symbol ------- means that the corresponding bonds a, b, c, d, e, f, g, h and i are single or double bonds, with the proviso that when b or f are a double bond, the group R_5 is absent; their pharmaceutically acceptable salts and esters.

2. (twice amended) A [B]benzo(c)quinolizine compound[s] of formula (1) according to Claim 1, wherein R_5 = H, C_{1-8} alkyl-phenyl, biphenyl, naphthyl, saturated or aromatic heterocycle containing one [or more] to three N atoms, C_{1-8} alkyl-saturated or aromatic heterocycle containing one [or more] to three N atoms; or a C_{1-8} alkyl-saturated or aromatic heterocycle containing one [or more] to three N atoms-ribose-phosphate;
X = O, COOH;
Q = single bond, CO, CONR, NR, wherein R
is chosen from the group consisting of H, C_{1-8} alkyl, cyclopropane, cyclobutane, cyclopentane, cyclohexane,

cycloheptane, cyclooctane, norbornane, canphane, adamantane, phenyl, biphenyl, naphthyl, saturated or aromatic heterocycle containing one [or more] to three N atoms, naphthyl-C_{1-8}alkyl;
W = H, F, Cl, Br, Me, t-butyl, C_{1-8}alkoxy, 2,5-dimethylhexyl, trifluoromethyl, 2,5-(di-trifluoromethyl)-phenyl, 4-methyloxy-phenyl, phenyl, phenyl-C_{1-8}alkyl, C_{1-8}alkylcarbonyl, phenylcarbonyl;
n = 1 and 2;
R_1, R_2, R_3, R_4 and R_6 = H, Me, CN, phenyl, COOR, CONRR', C(=O)R, wherein R and R'are the same or different and are chosen from the group consisting of H, C_{1-8} alkyl, cyclopropane, cyclobutane, cyclopentane, cyclohexane, cycloheptane, cyclooctane, norbornane, canphane, adamantane, phenyl, biphenyl, naphthyl, saturated or unsaturated heterocycle containing one [or more] to three N atoms, naphthyl-C_{1-8}.

10. (amended) A [P]pharmaceutical composition wherein the active principle is a compound of formula (I) according to Claim 1 or mixtures thereof in combination with [the] suitable pharmaceutically acceptable excipients.

28. (amended) A [F]fully and partially reduced benzo(c)quinolizine compound[s] of formula (1):



(I)

wherein:
R_1, R_2, R_3, R_4 and R_6, which are the same or different, are chosen from the group consisting of: H, C_{1-8} alkyl, C_{2-8} alkenyl, C_{2-8} alkynyl, cyclopropane, cyclobutane, cyclopentane, cyclohexane,

cycloheptane, cyclooctane, norbornane, camphane, adamantane, phenyl, biphenyl, naphthyl, saturated or unsaturated aromatic heterocycle containing one N atom, halogen, CN, azide, NRR', C_{1-8} alkylamino, arylamino, C_{1-8} alkyloxy, aryloxy, COOR, CONRR', C(=O)R, wherein R and R', which are the same or different, are chosen from the group consisting of H, C_{1-8} alkyl, cyclopropane, cyclobutane, cyclopentane, cyclohexane, cycloheptane, cyclooctane, norbornane, camphane, adamantane, phenyl, biphenyl, naphthyl, saturated or unsaturated heterocycle containing one N atom, naphthyl-C_{1-8};

R_5 is chosen from the group consisting of: H, C_{1-8} alkyl, C_{1-8}alkyl-phenyl, biphenyl, naphthyl, COOR, CN, phenyl, saturated or aromatic heterocycle containing one N atom, C_{1-8} alkyl-saturated or aromatic heterocycle containing one N atom; C_{1-8} alkyl saturated or aromatic heterocycle containing one N atom-ribose phosphate;

X is chosen from the group consisting of: O, C(=O)R, COOR, NO_2, and CONNR', wherein R and R' are as above defined;

Q is chosen from the group consisting of single-bond, C_{1-8} alkyl, C_{2-8} alkenyl, C_{2-8} alkynyl, cyclopropane, cyclobutane, cyclopentane, cyclohexane, cycloheptane, cyclooctane, norbornane, camphane, adamantane, CO, CONR, and NR, where R is as above defined;

W is chosen from the group consisting of H, C_{1-8} alkyl, C_{2-8} alkenyl, C_{2-8} alkynyl, cyclopropane, cyclobutane, cyclopentane, cyclohexane, cycloheptane, cyclooctane, norbornane, camphane, adamantane, trifluoromethyl, C_{1-8} alkoxy, C_{1-8} alkoxy-C_{1-8} alkyl, phenyl, biphenyl, naphthyl-C_{1-8} alkyl, phenyl, biphenyl, naphthyl, phenyloxy, biphenyloxy, naphthyloxy, phenylamino, biphenylamino, naphthylamino, C_{1-8} alkyl-carbonyl, phenylcarbonyl, biphenylcarbonyl, naphthylcarbonyl, phenylcarboxyl, biphenylcarboxyl, naphthylcarboxyl, phenylcarboxyamide, biphenylcarboxyamide, naphthylcarboxyamide, halogen, CN, NRR', C_{1-8} alkylamino, saturated or aromatic heterocycle containing one N atom wherein the groups alkyl, alkenyl, alkynyl, cyclopropane, cyclobutane, cyclopentane, cyclohexane, cycloheptane, cyclooctane, norbornane, camphane, adamantane, phenyl, biphenyl,

naphthyl, saturated or aromatic heterocycle containing one N atom, can be substituted;
n is an integer comprised between 1 and 4;
the symbol ------- means that the corresponding bonds a, b, c, d, e, f, g, h and i are single or double bonds, with the proviso that when b or f are a double bond, the group R_5 is absent; their pharmaceutically acceptable salts and esters.